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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/542,520 | 04/03/2000 | W. James Jackson | 7969-076-999 | 4570 |

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| EXAMINER |
|---|
| TURNER, SHARON L |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1647 | |

DATE MAILED: 10/22/2002

43

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/542,520 | JACKSON ET AL. | |
| | Examiner | Art Unit | |
| | Sharon L. Turner | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sh et with th correspond nce address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 July 2002* .

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *48-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 April 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6 12 17* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

1. The amendment filed 7-17-02 has been entered into the record and has been fully considered.

2. Claims 21-22, 32-37 and 42-47 are canceled. New claims 48-57 are pending. It is noted that claims 58-62 to which applicants refer are not present.

### Drawings

3. The drawings are objected to under 37 CFR 1.83(a) because they fail to show particular details. In Figure 1, the three immunoreactive bands detected in EBs and RBs as described in the specification, specifically the brief description of Figure 1 are not viewed from the photocopy. In Figure 7A and 7B, the indirect immunofluorescence cannot be viewed in the photocopy and the reference to that staining which is yellow is not represented by the black and white photocopy. The specification should be amended to reference Figure 7A and 7B in the brief description of the drawings. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### Election/Restriction

4. Applicant's election with traverse of Group I, claims 48-57 to the extent of the protein of SEQ ID NO:2 in Paper No. 20 is acknowledged. The traversal is on the ground(s) that the peptides designated as SEQ ID NO's 2, 15 and 16 share substantial homology in the range of 95% or more identity and that therefore the searches are co-

extensive. This is not found persuasive because the inventions are distinct as set forth. The peptides differ in structure, associated effects, functions and are capable of different use. A search of any one of the SEQ ID NO's would not necessarily reveal all pertinent art with respect to the other and therefore search and examination of the multiple inventions within a single application represents a significant burden to the Examiner. At this time there is no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

**Claim Objections**

5. Claims 48-52 and 54-57 are objected to as reciting an improper Markush Group. M.P.E.P. 803.02 states that:

> "Since the decisions in In re Weber **,198 USPQ 328 (CCPA 1978); and In re Haas, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, In re Harnish , 631 F.2d 716, 206 USPQ 300 (CCPA 1980); Ex Parte Hozumi , 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility."

In the instant case the various peptides as claimed lack common structural features which are shared amongst all members and which are common to the essential utility.

**Claim Rejections - 35 USC § 112**

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:
> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 54-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicants point to support for new claim 54 at p. 28-33, in in particular at p. 29, lines 8-25. However, the support at these passages fails to provide specific support for the claim recitations, a nucleic acid "which hybridizes under conditions comprising 50% formamide and 37° C or 0.15M NaCl and 70° C to a DNA sequence of SEQ ID NO:1, 23 or 24, or a sequence complementary thereto; and which HMW protein is recognized by an antibody that specifically binds to a peptide comprising an amino acid sequence of SEQ ID NO:2, 15 or 16." The recited hybridization conditions are not found in the specification at the cited passages and moreover support is not found for the selection of those nucleic acids which hybridize under the recited conditions and which encode a protein which is recognized by an antibody that specifically binds to a peptide comprising an amino acid sequence of SEQ ID NO:2. Support for the particular combination of elements appears to be lacking. Thus, the recitations constitute new matter absent evidentiary support in the specification as originally filed.

Claims 54-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for particular nucleic acids which hybridize to the complementary strand of SEQ ID NO:1 and encode peptides capable of similarly reacting with the peptide of the coding strand, does not reasonably provide enablement

for nucleic acids which hybridize to the coding strand. These peptides are not recognized as being capable of encoding a peptide of sufficient similarity that the peptide so as to be capable of stimulating antibodies capable of binding to SEQ ID Nos 2 as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claim is directed to "a nucleic acid sequence which hybridizes" under the particularly noted conditions "to SEQ ID NO.1, 23 or 24 or a sequence complementary thereto and encodes a protein which is recognized by an antibody that specifically binds to a peptide comprising an amino acid sequence of SEQ ID NO:2, 15 or 16" as recited in the claim. However, it is noted that only the coding strand is capable of producing an antibody that specifically binds to a peptide as noted in the claim. The non-coding or complementary sequence, while capable of hybridization, encodes a peptide completely unrelated to SEQ ID NO's 2, 15 and 16 due to the genetic code which specifies unique amino acids based upon the nucleic acid structure. Thus, the particular hybridizing nucleic acids to the coding strand would not enable the artisan to make or use a nucleic acid in scope with the requirements of the claim as the sequences would not be expected to be capable of encoding a peptide capable of producing an antibody which would specifically react to the amino acids of SEQ ID NO's 2, 15 and 16.

Further with respect to the recitation of hybridizing sequences which would encode partial fragments and analogues of SEQ ID NO:2, the skilled artisan recognizes that even in short peptides that single amino acid exchanges can eliminate antibody

stimulation, recognition and binding, in addition to peptide function in an unpredictable manner, see in

The specification fails to teach any analogue or analogue fragments generated by hybridizing sequences which retain immunoreactivity as required. It is further noted that a substantial portion of the hybridizing sequences are unable to encode a peptide sharing any significat amino acid structure with SEQ ID NO:2

In view of the lack of guidance, lack of examples, and lack of predictability associated with producing similar peptides using hybridizing nucleic acids and the quantity of experimentation required to find any one member capable of both hybridizing and encoding as claimed, one skilled in the art would be forced into further undue experimentation in order to determine those nucleic acids which correlate in scope to the claim recitations i.e., to define which residues are responsible for antibody specificity and determining any particular nucleic acid sequence capable of hybridizing with and encoding the relevant amino acids.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 54-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 54 is indefinite because the duplicative uses of "or" followed by "and". The sentence structure creates alternative interpretations of the hybridization conditions,

nucleic acid elements and whether or not they are required to encode a protein which is recognized by an antibody as claimed. The claims should be amended to clarify the alternative hybridization conditions, sequence elements and to which (or all) of the elements are required to "encode a protein which is recognized by an antibody". It is noted that the complementary strand would not be readily recognized as a sequence capable of encoding a protein which is recognized an antibody to SEQ ID NO:2, see in particular enablement rejection as noted above.

**Claim Rejections - 35 USC § 102**

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 48-57 are rejected under 35 U.S.C. 102(e) as being anticipated by Daniels et al., US 5,725,863, 10 March 1998.

Daniels et al., teach isolated Chlamydia polypeptides ranging from molecular weights 40 to 140kDa which are pharmaceutically useful for the prevention of

chlamydial infection. The polypeptides were purified via SDS-PAGE, see in particular Examples 7 and 8. The Chlamydia may be either psittaci or trachomatis, see in particular column 4, lines 18-28. The peptides are antigenic and stimulate an immune response in a mammal, may be used for the production of antibodies and for treatment of Chlamydial infections, see in particular Example 1 and 9. The vaccine composition may comprise the isolated peptides, pharmaceutical carriers and adjuvants, see in particular claims 3 and 5. Daniels also discloses that the "high degree of antigenicity and cross-reactivity of this polypeptide gives evidence of its ability to stimulate a strong immune response when purified and mixed with a suitable adjuvant. These polypeptides were rehydrated with RIBI adjuvant, MPL+TDM+CWS to make the test vaccine. Three injections were given to four guinea pigs weighing approximately 700 g. These consisted of two injections of 0.2 cc given subcutaneously, in two different sites and one injection of 0.1 cc given intraperitoneally for a total of 1 mg protein." Thus, although not explicitly stated the injection of the composition is evidenced to be by emulsion. Although the peptides of Caldwell are not delineated by amino acid sequence the isolated peptide fraction is deemed to inherently comprise the amino acid sequence of SEQ ID Nos 2 as the fraction is isolated from the same Chlamydial species via the same method of SDS-PAGE electrophoresis, and corresponds in molecular weight to the isolated peptide fraction of applicants specification, i.e., MW 40-140 of Caldwell comprises MW 105-115 kDa MW of applicants claims. As the peptides are necessarily the same, the nucleic acid sequence is deemed to be inherent, absent convincing factual evidence to the contrary. It is noted that the claims drawn to peptides encoded

by nucleic acids or to peptides obtained via the deposited plasmids are included within the rejection as the limitations are product by process limitations and thus are not deemed to patentably distinguish the product made or isolated via an alternative method such as by SDS-PAGE electrophoresis as in Daniels.

12. Claims 54-57 are rejected under 35 U.S.C. 102(e) as being anticipated by Sim et al., US 5,849,306, 15 December 1998.

Sim et al., teach polynucleotides encoding plasmodium falciparum erythrocyte binding proteins. The peptides are disclosed as being useful for vaccination via administration of the peptides with an adjuvant in an emulsion preparation, see in particular columns 3-4 and 15-17 for pharmaceutical preparations including emusions including lipid adjuvants. The administration can be to human, see in particular columns 15-16. The nucleic acids of Sim, in particular residues 4436-4416 of SEQ ID NO:11 shares 100% similarity with instant SEQ ID NO: 1, residues 3470-3490 and thus encodes a 6mer of SEQ ID NO:2 which may be recognized by an antibody to SEQ ID NO:2 as the sequence exhibits an epitope (6mer) of instant SEQ iD NO:2. The peptide hybridizes to SEQ ID NO:1 as it shares 21 nucleotides in common with a Tm=4(G+C)+2(A+T) of 52 degrees Celsius and thus would necessarily hybridize under conditions of 37 degrees as claimed. Thus, the reference teachings anticipate the claimed invention.

**Status of Claims**

13. No claims are allowed.

14. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
October 21, 2002